K123822

5. 510(k) Summary

Submitter:	HK Surgical, Inc.	
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Contact person:	Pejman Farivar	
Date prepared:	12/10/2012	
510(k) Number:	To be Determined	
Trade name:	KleinTouch Pump (KTP)	
Common name:	Infiltration Pump	
Classification name:	Pump, Infusion SEP 27 2013	
Classification:	Product Code: FRN, Regulation Number: 880.5725 Class II	
Substantial equivalence claimed to:	Klein Infiltration Pump – K031432	
Description:	Device Functionality:	
	The KleinTouch Pump is an electrically or battery operated, manually controlled, peristaltic pump using three rollers to create pumping action in a section of sterile tubing.	
	Scientific Concept(s)	
	The KTP is designed to specifically function with sterile single use only Klein Touch Tubing (KT20). Tubing must be primed before use. Please refer to the KT20 Instructions for Use for further details.	
	Physical And Performance Characteristics	
	Device Design	• Display: Color Graphic LCD • Dual Foot Switches With Hose - Air Activated • Dimensions: 11" x 10 ¾" x 5" • Weight: 8.4 lbs.
	Components Used	• Motor • Fluid Pathway Materials • Silicone • Inlet Hospital Power Cord • Hospital Grade Plugs • Barcode Reader • Base, Plastic • Battery • Instrument Foam • PCBA - Power Board • PCBA, Main Circuit Board • Pump, Peristaltic, 3-Roller, Fixed Clamp • Switch, Rocker, Lighted
	Physical Properties	The Pump is intended for use in combination with the KT20 tubing. The peristaltic pump using three rollers will create pumping action in KTP20 tubing set

	specifically designed for the KleinTouch Pump
Intended use:	The KleinTouch Pump is an infiltration pump used to cause a flow of fluid from an IV bag into a patient in a manner controlled manually by a health care professional. The KleinTouch pump is not intended to be used as an IV infusion pump.
Safety and Labeling	**WARNINGS AND CAUTIONS** The device labeling contains cautions and warnings which are considered essential to the safety of personnel, patients, equipment, and property. This device must be used by a trained professional with current knowledge regarding safety of total dosage. Orders for dosage must be by a physician and legible. Protection against electric shock: Class I, Type B *Refer to the Instructions for Use for the Pump and Infusion Set for Warnings and cautions.*
Performance Testing	**MET LABS** tested per UL Standards 2601-1; 2nd ed. Medical Electrical Equipment- Part 1 General Requirements for Safety • CSA C22.2 • UL 60601-1 • EN/IEC 60601-1 **EMC:** • IEC/EN 60601-1-2:2007-ED30 • JSA-JIS T0601-1-2:2002 • AS/NZ 3200.1.2:2005 Biocompatibility Testing demonstrates all fluid path materials are biocompatible in accordance with ISO10993-1. Sterilization Validation to SAL 10^{-6} in accordance with ISO11135. Human Factors evaluation demonstrates the KleinTouch Pump can be used safely with no critical task errors. Performance testing demonstrates the KleinTouch Pump meets the specifications.

Substantial Equivalence Conclusion:

HK has provided test data to assess the technological differences and demonstrate Subject Device is substantially equivalent to the predicate device (K031432) and at least is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 27, 2013

HK Surgical, Inc.
Ms. Clare Bennett
General Manager
1271 Puerta del Sol
SAN CLEMENTE, CA 92673

Re: K123822
Trade/Device Name: KleinTouch Pump (KTP)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: February 1, 2013
Received: February 1, 2013

Dear Ms. Bennett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

The KleinTouch Pump is an infiltration pump used to cause a flow of fluid from an IV bag into a patient in a manner controlled manually by a health care professional. The KleinTouch pump is not intended to be used as an IV infusion pump.

Prescription Use ☑ **AND/OR Over-The-Counter Use** ____

(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Richard C. Chapman
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